



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,389	12/13/2005	J Michael Palmowski	0380-P03220US1	2535
110 7590 04/01/2009 DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307				
EXAMINER				
BLUMEL, BENJAMIN P				
ART UNIT		PAPER NUMBER		
1648				
MAIL DATE		DELIVERY MODE		
04/01/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/560,389

Applicant(s)

PALMOWSKI ET AL.

Examiner

BENJAMIN P. BLUMEL

Art Unit

1648

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/7/09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 38-45 is/are pending in the application.
- 4a) Of the above claim(s) 3-6, 8, 9, 11, 12, 15-30, 38 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 7, 10, 13, 14, 39-41 and 43-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments. Claims 1, 2, 7, 10, 13, 14, 39-41 and 43-45 are examined on the merits. Claims 39-41 and 43-45 are new claims with newly recited limitations.

Election/Restrictions

This application contains claims 4-6, 8, 9, 11, 12 and 15-30 are drawn to an invention nonelected with traverse in the reply filed on January 22, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Newly submitted claims 38 and 42 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 38 and 42 require that a tumour associated antigen is expressed.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 38 and 42 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

Applicant's arguments filed January 7, 2009 have been fully considered but they are not persuasive. See response below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(New Rejection Necessitated by Amendments) Claims 1, 2, 7, 10, 13, 14, 39-41 and 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Rovinski et al. (US PGPub 2002/0051770 A1).

The claimed invention (claims 1, 2, 7 and 10) is drawn to a method of stimulating an immune response to an antigen in an individual by a heterologous prime-boost immunization protocol, the method comprising the steps of:

- i) administering to the individual a plasmid or other expression vector, which encodes said antigen to prime said immune response;
- ii) administering to the individual a lentivirus engineered to comprise exogenous nucleic acid encoding said antigen to boost the primed immune response. The exogenous nucleic acid encodes a pathogen-derived antigen, such as a lentiviral antigen

The claimed invention (claims 13 and 14) also includes a method of administering lentivirus particles, which encode said antigen, to an individual in order to boost a pre-existing immune response that was elicited by the administration of a nucleic acid also encoding said antigen. However, for purposes of examination, this alternative method involving the boosting of a pre-existing immune response is interpreted to be within the same scope as that of the prime/boost method of claim 1.

Response to arguments:

Applicants argue that Rovinski et al. use endogenous antigens in their prime-boost method.

Rovinski et al. teach a prime-boost method of inducing an antibody response to HIV antigens, particularly the envelope glycoprotein. In order to induce such an immune response, Rovinski et al. teach to prime with plasmids encoding the envelope glycoprotein, and then boost with non-infectious, non-replicating HIV-like particles (VLPs) that encode this envelope glycoprotein. Rovinski et al. also teach that in creating the VLPs, certain genes/proteins can be modified or may be obtained from different HIV isolates. For example, Rovinski et al. teach that the ENV gene from the BX08 isolate can be employed in VLPs and that the GAG and POL gene of a modified HIV genome (which is used to make VLPs) can originate from the same or different isolates. Therefore, Rovinski et al. anticipate the claimed invention. *See abstract and paragraphs [5, 10, 11, 17-20, 40 and 41].*

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/
Primary Examiner, Art Unit 1648

/BENJAMIN P BLUMEL/
Examiner
Art Unit 1648